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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/408,142	09/29/1999	MASAHARU MUKOUYAMA	HIRA1140	3645

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/05/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/408,142

Applicant(s)

Mukouyama et al

Examiner

Irene Marx

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 14, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-13, and 15-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-13, and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

The application should be reviewed for errors. Error occurs, for example in claims 1 and 10, line 4, in the spelling of "soution"; in the spelling of "contianing" in claim 10, penultimate line; in the lack of the article "a" at line at line 6 before "fumaric acid aqueous suspension" and in the lack of the article "a" (or "the") before "suspension" at line 12, in claim 1; line 11 in claim 10 and line 2 of claim 20.

Since this application is eligible as a Continued Prosecution Application under 37 CFR 1.153(d), the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.153(b). Applicant's submission after final filed on 9/24/01 has been entered.

Claims 1-8, 10-13 and 15-20 are being examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10-13 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation in claims 1, 5 and 10 of "fumaric acid dry crystals, moisture containing fumaric acid or fumaric acid aqueous suspension" in this context. In addition, no clear basis or support is found for infinite recycling as recited in claim 18.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10-13 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 10 are vague, indefinite and confusing in the recitation of "a temperature of said solution reaches a range of between 50 to 130°C" at line 5. Do applicants mean "the temperature... reaches between 50° and 130°C" and is ^{the solution} maintained at a temperature within the range? Or do applicants intend that the temperature fluctuates between 50° and 130°C? The use of "a temperature" at line 4 in this context is puzzling.

The distinction between "cooling" and "permitting cooling" is uncertain. The recitation appears redundant in claims 1 and 10.

Claim 1 is confusing in that the antecedent basis for "fumarate" at line 8 of claim 1 is uncertain. Is it ammonium L-fumarate or fumaric acid? If it is intended to be "fumaric acid", "fumarate" lacks proper internal antecedent basis.

Claims 5 and 10 are confusing in that the antecedent basis for "thereto" is uncertain in this context.

Claim 5 fails to find proper antecedent basis in claim 1 for a "cooling step". In addition it cannot readily be ascertained how the temperature rate is to be calculated or assessed.

Claim 10 is vague and indefinite in the use of the phrase "to crystallize L-aspartic acid for crystallizing L-aspartic acid"

Claim 17 is confusing in that from the context it is uncertain what is intended by "a substrate solution". If applicants intend to use the mother liquor as a source of ammonium fumarate, the claim should be amended accordingly. Also the intended meaning of "a mother liquor" in claims 17-18 is uncertain. Is "the mother liquor" intended?

The intended meaning of "a washing liquid" in claim 19 is unclear. Also the nature of the "recycling" step is not delineated with sufficient particularity.

With respect to the molar ratio in claims 1 and 10, the basis to be used for the calculation of the molar ratio cannot be readily assessed since the phrase "adding... in a molar ratio of 0.4 to 0.8 to the total amount of fumarate and the L-aspartate contained therein" is not clear.

Also, the phrase in claims 1 and 10 regarding “fumaric acid dry crystals, moisture - containing fumaric acid crystals, or fumaric acid aqueous suspension”, renders the claims confusing, inasmuch as the distinction between “moisture containing” and “aqueous suspension” is not clear, even when reading the claims in light of the specification. See also the new matter rejection *supra*.

Moreover, the recitation in claim 8 of “wherein the crystallization step is performed by a continuous method”, renders the claim confusing. For example, the antecedent basis for “the crystallization step” in claim 1 is not clear.

Claim 1 fails to find proper internal antecedent basis for “said solution between...”, since the claim is directed to a “homogeneous solution”. Thus, in claim 3 the proper antecedent basis for “said homogeneous solution is maintained” is uncertain.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nore *et al.* taken with Brun *et al.*, Pavia *et al.* and Tan *et al.* for the reasons as stated in the last Office action and the further reasons below.

Nore *et al.* teaches a method of producing aspartic acid wherein fumaric acid is added to ammonium aspartate followed by heating to about 50°C and crystallization of a homogenous solution at a temperature of about 25° to 100°C (See, e.g., examples).

The reference differs from the invention as claimed in that the ammonium aspartate solution is not produced by enzymatic means from ammonium fumarate. However, the reference discloses that this is an advantageous method, since it permits recycling of ammonium fumarate produced in the crystallization process (See, e.g., column 2, lines 23-52). With respect to the cooling rate of the precipitation reaction, the reference indicates that the temperature drops 20°C in 15 minutes, which appears to correspond to the rate as claimed. Even if it is not, it is submitted that the adjustment of the cooling rate for optimization of the crystallization process would have been within the purview of the ordinary artisan in this art.

In addition Brun *et al.* teach a similar process using a temperature of 135°C and gradual cooling of the reaction productions (See, e.g., examples). In addition the reference teaches the crystallization process of aspartic acid in the presence of ammonium fumarate (See, e.g., Examples 6).

The references differ from the claimed invention in that a process of crystallization using reduced pressure and recycling of the evaporated water is not disclosed. However, Pavia *et al.* adequately demonstrate that it is routine in the art of crystallization to remove the solvent used in the crystallization process by a variety of processes, which include reduced pressure, such as by using a vacuum desiccator (See, e.g., page 514). Moreover, Tan *et al.* demonstrate the use of condensing and recycling to maximize the yield of crystallized product (See, e.g., Example 1).

Therefore, one of ordinary skill in the art would be motivated to use reduced pressure to remove water from the crystallizing solution of aspartic acid and recycle the water obtained by returning it to the reaction vessel with a reasonable expectation of success of obtaining a favorable yield of crystalline aspartic acid.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process taught by Nore *et al.* by adjusting the reaction and crystallization temperatures according to the teachings of Brun *et al.*, if necessary, and by using the crystallization protocols suggested by Pavia *et al.* and Tan *et al.* for the expected benefit of maximizing the yield of pure aspartic acid useful for nutritional purposes and as an intermediate in the production of further amino acids and of proteins.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In response to Applicant's arguments regarding "a time frame for the cooling to optimize crystallization", with all due respect, it is noted that the Nore reference indicates that the temperature drops 20°C in 15 minutes, which appears to correspond to the rate as claimed. Applicant's argument that it is a time of "stirring" and not "cooling" is not persuasive because stirring surely cools the solution. Applicant's attention is also directed to the rejections under 35 U.S.C § 112, second paragraph, regarding the clarity of the claim limitations. That Brun

indicates a preferred temperature of 20°C does not invalidate the gradual cooling disclosed by Nore, as contended (Response, page 8).

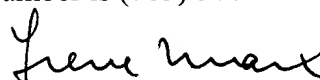
Applicant appears to rely on the gradual cooling process as the crux of the invention. Yet this seemingly critical limitation is recited in claims 5 and 10 only and in a confusing manner. As noted supra, at least the antecedent basis for "thereto" in claims 5 and 10 is uncertain. The specification at page 4, paragraph 3 indicates that the rate of cooling should be between 0.1 and 5°C per minute after the addition of fumaric acid to the ammonium L-aspartate solution to deposit L-aspartic acid crystals of desirable purity.

Therefore the rejection is deemed proper and it is adhered to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
Art Unit 1651